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Item: 3151

FACT SHEET

Microbial Products of Biotechnology: Final Regulations Under the Toxic Substances Control Act

Summary

EPA is publishing final rules which fully implement its screening program for new microorganisms under Section 5 of the Toxic Substances Control Act (TSCA) . These regulations tailor to microorganisms the screening program that has been in place since 1986 for microbial products of biotechnology. They establish a separate part in the Code of Federal Regulations for microbial products of biotechnology subject to TSCA, 40 C.F.R. Part 725; create a number of exemptions; and codify EPA's approach to research and development (R&D) for microbial products of biotechnology. These rules provide significant regulatory relief to those wishing to use certain products of microbial biotechnology. At the same time, these rules are designed to ensure that EPA can adequately identify and regulate risk associated with microbial products of biotechnology without unnecessarily hampering this important new industry.

This fact sheet summarizes the key components of the final rules, "Microbial Products of Biotechnology; Final Regulations Under the Toxic Substances Control Act". For more details, please refer to the accompanying Federal RegisterNotice.

Microorganisms Subject to These Rules

Microorganisms subject to this rule are "new" microorganisms used commercially for such purposes as production of industrial enzymes and other specialty chemicals; agricultural practices (e.g., biofertilizers); and break-down of chemical pollutants in the environment.

These rules continue the interpretation of "new" microorganism first put forth by EPA in 1986. New microorganisms are those microorganisms formed by combining genetic material from organisms in different genera (intergeneric). A genus (pl. genera) is a level in a classification system based on the relatedness of organisms. EPA believes that intergeneric microorganisms have a sufficiently high likelihood of expressing new traits or new combinations of traits to be termed "new" and warrant review. Microorganisms that are not intergeneric would not be "new", and thus would not be subject to reporting under Section 5 of TSCA.

Reporting Requirements

These regulations create a reporting vehicle specifically designed for microorganisms, the Microbial Commercial Activity Notice (MCAN). Persons intending to use intergeneric microorganisms for commercial purposes in the United States would submit an MCAN to EPA at

least 90 days before such use. EPA has 90 days to review the submission in order to determine whether the intergeneric microorganism may present an unreasonable risk to human health or the environment.

The rules also address intergeneric microorganisms used in R&D for commercial purposes and creates a vehicle for reporting on testing of new microorganisms in the environment, a TSCA Experimental Release Application (TERA). A TERA would be submitted to EPA at least 60 days prior to initiating such field trials. The TERA is designed, in recognition of the needs of researchers, to provide a high measure of flexibility and a shorter review period (60 days). R&D for commercial purposes are those activities which are funded directly, in whole or in part, by a commercial entity regardless of who is actually conducting the research; or which will obtain for the researcher an immediate or eventual commercial advantage.

Exemptions

Certain intergeneric microorganisms would be exempt from the requirement to submit a MCAN if the manufacturer meets criteria defining eligible microorganisms and specified use conditions. This exemption is most applicable to the manufacture of specialty and commodity chemicals, particularly industrial enzymes.

Intergeneric microorganisms used at R&D in contained structures are exempt from EPA reporting requirements, if researchers maintain records demonstrating eligibility. Researchers are exempt from this record keeping requirement when the researcher or institution is in mandatory compliance with the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules". Those researchers voluntarily following the NIH Guidelines can, by documenting their use of the NIH Guidelines, satisfy EPA's requirements for testing in contained structures. Alternatively, researchers can take the exemption by documenting that they meet eligibility criteria laid out by EPA in these rulemakings.

Certain intergeneric microorganisms in R&D field testing are also exempt. Testing on ten acres or less involving *Bradyrhizobium japonicum* and *Rhizobium meliloti* is exempt when certain exemption criteria specified by these rules are met.

Electronic Availability of Documents

EPA anticipates that these final rules will be of widespread interest to the general public as well as to all sectors of the biotechnology community. As a result, in an effort to provide as broad access as possible to the rules, the Agency is making a version of the final rules, as well as certain support documents available electronically to the public. These documents may be accessed through the Internet at the Office of Pollution Prevention and Toxics' Biotechnology Program homepage at: http://www.epa.gov/opptintr/biotech/. Alternatively, the documents are available from the EPA home page at the Environmental Sub-Set entry for this document under "Regulations" (http://www.epa.gov/fedrgstr/). Fax-On-demand: Using a faxphone call 202-401-0527 and select item 3100 for an index of available material and corresponding item numbers related to these documents.